REMARKS/ARGUMENTS

The Office Action mailed November 14, 2003 has been reviewed and carefully considered. Claim 18 is canceled. Claims 10, 11, and 20 have been amended. Claims 1-17 and 19-20 are pending in this application, with claims 1, 10 and 11 being the only independent claim. Reconsideration of the above-identified application, as herein amended and in view of the following remarks, is respectfully requested.

In the Office Action mailed November 14, 2003, claims 10, 14, 17, and 18 are objected to because it is unclear how the localization means differs from the data processing means. The data processing and display means receives information from a variety of sources and displays the information on a display. Independent claim 10 is amended to clarify that the data processing and display means determines the location of the end zone based on the localization means and displays the location in the survey image. The data processing and display means also receives information from the imaging acquisition device for display. In view of the amendments, it is respectfully submitted that the role of the processing and display means is now sufficiently clear.

Claim 18 is also objected to as failing to provide antecedent basis for "the first section". Claim 18 has been canceled. In view of the above amendments and comments, it is respectfully submitted that the objections to claims 10, 14, 17, and 18 now be withdrawn.

Claims 13-15 stand rejected under 35 U.S.C. §112, first paragraph, as failing to provide an adequate description of the claim limitations in the specification to enable one skilled in the art to make and/or use the invention.

Regarding enablement, the MPEP §2106.01 states: "When basing a rejection on the failure of the applicant's disclosure to meet the enablement provisions of the first paragraph of **35 U.S.C. 112**, the examiner must establish on the record that he or she has a reasonable basis for

questioning the adequacy of the disclosure to enable a person of ordinary skill in the art to make and use the claimed invention without resorting to *undue experimentation*. See *In re Brown*, 477 F.2d 946, 177 USPQ 691 (CCPA 1973); *In re Ghiron*, 442 F.2d 985, 169 USPQ 723 (CCPA 1971). The question for enablement is whether the disclosure is sufficient to enable those skilled in the art to practice the claimed invention, hence the specification need not disclose what is well known in the art. See *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 221 USPQ 481, 489 (Fed. Cir. 1984).

The rejection of claims 13-15 as non-enabled states that the specification fails to disclose a computer program for executing the method or for controlling the devices set forth in the claims. However, a disclosure of the actual program itself is not required. In *Northern Telecom v. Datapoint Corp.*, 908 F.2d 931, 15 USPQ2d 1321, claims to a computer program for implementing a method and controlling a device were found to be enabled, even though the actual program was not disclosed. Accordingly, the lack of disclosure of the computer program alone is not enough to reject claims 13-15 and the Examiner has not provided a reasonable basis for questioning the adequacy of the disclosure. It is respectfully submitted that the disclosure of the steps of the method and the functions of the devices within the current specification is adequate to enable one skilled in the art of computer programming to develop the computer programs as recited in claims 13-15. Accordingly, it is respectfully submitted that claims 13-15 are enabled by the present disclosure.

Claim 13-15 are also rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claimed invention subject matter need not be described literally, i.e., using the same terms, in order for the disclosure to satisfy the description requirement. Software aspects of inventions may be described functionally. See

Robotic Vision Sys. v. View Eng'g, Inc., 112 F.3d 1163, 1166, 42 USPQ2d 1619, 1622-23 (Fed. Cir. 1997); *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997); *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1537-38, 25 USPQ2d 1241, 1248-49 (Fed. Cir. 1992). In the present application, page 5, lines 3-6, of the specification indicate that the invention relates to a computer program for executing the method and controlling the devices of the invention. It is respectfully submitted that the remainder of the specification, specifically, page 5, line 7 to page 9, line 6, adequately describe the functions required of the computer programs and therefore complies with the written description requirement.

In view of the above remarks, it is respectfully submitted that the rejections of claims 13-15 under 35 U.S.C. §112, first paragraph, now be withdrawn.

Claims 11, 12, 15, and 18 stand rejected under 35 U.S.C. §103 as unpatentable over U.S. Patent No. 5,638,819 (Manwaring).

Before discussing the cited prior art and the Examiner's rejections of the claims in view of that art, a brief summary of the present invention is appropriate. The present invention relates to a method for determining the position of a medical instrument introduced into an object, i.e., a patient, to be examined and for imaging the vicinity of the medical instrument. More specifically, the present invention relates to determining the position of a flexible medical instrument introduced into the object (see page 2, lines 15-19 of the specification). An end zone of the medical instrument includes an image acquisition device 4 and localization device 5 (page 5, lines 12-14). As shown in Fig. 1, the end zone is a section of the medical instrument that is proximate the tip that is inserted into the object.

The localization device 5 cooperates with a coil array 7 arranged beneath the patient (page 5, lines 20-26). Accordingly, the position of the end zone relative to the coil array can be determined. The image acquisition device 4 supplies image information concerning the vicinity of the image acquisition device 4 (page 5, lines 14-19).

A data processing device 12, determines, from the data received from the localization device 5 and the image acquisition device 4, a position of the localization device, i.e., the end zone of the medical instrument, in relation to a survey image defined by a stored image data set of the examination zone of the patient (page 6, lines 6-8). The image set may be formed directly before intervention or during an earlier diagnosis and is stored in a database 13 (page 6, lines 8-10). The image set may be four-dimensional with a temporal resolution such that different image sets may be obtained at different instants during cardiovascular motion phase (see page 3, lines 3-8). To determine the position of the end zone relative to the survey image in database 13, registration by suitable markers on the patient which are also present in the survey image is required (page 6, lines 10-14). The data processing device displays the survey image on a monitor 14 and the position of the end zone is superposed thereon (page 6, lines 16-19). The image from the image acquisition device 4 may also be displayed on the monitor 14 simultaneously (page 6, lines 19-22). Sensors measuring respiratory and/or cardiac motions may be used to compensate these motions during localization and imaging.

Independent claim 11 is directed to a medical instrument to be introduced into an object to be examined and has been amended to include the limitations of dependent claim 18. Independent claim 11 now recites "an instrument body having a base section that remains external to the object during use, an end zone that is to be introduced into the object during use of the medical instrument, and a flexible section arranged between the base section and the end zone

such that the end zone is movable relative to the base section". Since the instrument body is flexible, the position of the end zone can not be determined by the location of the base section.

It is respectfully submitted that Manwaring fails to disclose, teach or suggest (1) an instrument body having a base section that remains external to the object during use, an end zone that is to be introduced into the object during use of the medical instrument, and a flexible section arranged between the base section and the end zone such that the end zone is movable relative to the base section", and (2) a localization device arranged in the end zone, as recited in independent claim 11.

Manwaring discloses a medical instrument in which a sensor 30' is coupled to a localizer 26 for providing location of the medical instrument. The sensor 30' is fixed to a probe 12 having a shaft 34 and a probe tip 36. Manwaring expressly states that for "a given probe, tip 36 has a fixed spatial relationship to sensor 30'" (see col. 4, lines 26-28). The Examiner states that it appears that an endoscope used by Manwaring would inherently include a flexible section as is well known in the art. However, the determination of the position of the tip 36 using the sensor 30' would not be possible unless the shaft were rigid and the tip 36 was fixed with respect to the sensor 30'. Accordingly, the guidance system of Manwaring would not operate properly if a portion of the shaft 34 between the tip 36 and the sensor 30' were flexible. Accordingly, it is respectfully submitted that Manwaring fails to disclose, teach, or suggest "an instrument body having a base section that remains external to the object during use, an end zone that is to be introduced into the object during use of the medical instrument, and a flexible section arranged between the base section and the end zone such that the end zone is movable relative to the base section".

Furthermore, the Examiner maintains that it would have been obvious as an engineering design choice to place the sensor 30' at the tip. However, it is respectfully submitted that Manwaring fails to teach or suggest that the sensor 30' can be located on the end zone of the instrument that is inserted into the patient. In contrast, Manwaring shows the sensor 30' as external to the probe which would prevent it from being arranged in the end zone of the probe. Manwaring requires a complex sensor which indicates pitch, roll, and yaw so that the location of the tip of the instrument can be determined. Manwaring would have installed a sensor in the tip if it was possible to avoid using the complex sensor. Furthermore, Manwaring discloses a probe which is inserted within the skull of a patient. Accordingly, the size of the probe must be limited to the greatest possible extent. These disclosures of Manwaring actually teach away from installing a sensor in the probe tip.

It is critical in the present invention that the sensor be arranged at the probe tip to determine the location of the probe tip because the tip is connected to a base section of the instrument by a flexible section such that the probe tip is not fixed with respect to the base section. In contrast, Manwaring is able to determine the location of the probe tip within a patient by a sensor external to the patient because the shaft 34 of Manwaring is rigid. Accordingly, it is respectfully submitted that Manwaring fails to teach or suggest a localization device arranged in the end zone of the medical instrument that is inserted in the patient, as recited in independent claim 11.

In view of the above amendments and remarks, it is respectfully submitted that independent claim 11 is allowable over Manwaring. Dependent claims 12, 15, and 18, each being dependent on independent claim 11, are allowable for the same reasons as is independent claim 11.

The application is now deemed to be in condition for allowance and notice to that effect is solicited.

It is believed that no fees or charges are required at this time in connection with the present application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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